

**IN THE DRAWINGS:**

Please amend the Specification to cancel FIG. 15 from the application. Provided herewith are annotated sheets of FIG. 15 wherein is it noted that FIG. 15 is to be cancelled.

## REMARKS

The Office Action of February 11, 2011, has been received and reviewed. The claims are to be amended as previously set forth. All amendments are made without prejudice or disclaimer. No new matter has been presented. Reconsideration is respectfully requested.

### Drawings

Figure 15 is objected to as not being mentioned in the body of the Specification. Applicants request, *supra*, that Figure 15 be cancelled from the Specification. Further provided are annotated sheets of Figure 15 indicated that this figure is to be cancelled. In view of the amendment to the Specification, applicants request withdrawal of the objection

### Specification

The Specification was objected to as containing browser executable code. Applicants have amended the Specification herein to remove the objected to browser executable code.

The Specification was further objected to for reference to "Supplemental Data Tables" that assertedly did not appear to be part of the Specification as filed. In the Substitute Specification provided herewith, the references to "Supplemental Data Tables" have been deleted from the Specification.

### 35 U.S.C. § 112, Second Paragraph

Claims 49-54 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Applicants traverse the rejections as hereafter set forth.

Claim 49 stand rejected as referring to "step e)," wherein there is no "step e)" in the claim. Applicants have amended the claim to remove the reference to "step e)," thereby rendering the rejection moot.

Claim 50 stand rejected as containing a trademark/tradename. Applicants have amended the claims to remove the trademark/tradename, thereby rendering the rejection moot.

Claims 49-54 stand rejected as referring to Table 2. The Office notes that two of the Unigene sequences listed therein (HS.356623 and HS.454253) have been recited and there is no

additional information as to which gene is being referred to. Applicants have amended Table 2 herein to replace HS.356623 with BG420559. As indicated on the web page [http://telethon.bio.unipd.it/bioinfo/HGXP\\_170/Tissues/adipose\\_t\\_lib886.html](http://telethon.bio.unipd.it/bioinfo/HGXP_170/Tissues/adipose_t_lib886.html) (submitted herewith as accessed on June 2, 2011), the Unigene sequence of HS.356623 corresponds to BG420559. Further, applicants have amended Table 2 to replace HS.454253 with AK124593. As indicated on the web page [http://telethon.bio.unipd.it/bioinfo/HGXP\\_170/Tissues/ovary\\_t\\_lib510.html](http://telethon.bio.unipd.it/bioinfo/HGXP_170/Tissues/ovary_t_lib510.html) (submitted herewith as accessed on June 2, 2011), the Unigene sequence of HS.454253 corresponds to AK124593. The Applicants thus submit that no new matter has been added.

Claims 49-54 stand further rejected for omitting an essential step; to wit “obtaining a sample from and AML affected subject for which the prognosis is to be determined.” Applicants have amended the claims to recite “determining, in a sample obtained from the subject,” thus rendering the rejections moot.

In view of at least the foregoing, applicants submit that the rejection under 35 U.S.C. § 112, second paragraph have been overcome and request withdrawal of the rejections.

### **35 U.S.C. § 112, First Paragraph**

Claims 49-54 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to meet the enablement requirement. Specifically it was asserted that the claims lacked enablement for failing to recite obtaining a sample from an AML patient for which a prognosis was to be provided via the recited method. Applicants have amended the claims to recite “determining, in a sample obtained from the subject,” thus rendering the rejections moot.

In view of at least the foregoing, applicants submit that the rejection under 35 U.S.C. § 112, first paragraph have been overcome and request withdrawal of the rejections.

### **35 U.S.C. § 102**

#### **Schoch**

Claims 49-51 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Schoch *et al.* (PNAS 99(15):10,008-10,013) (hereafter “Schoch”). Applicants traverse the

rejections as hereinafter set forth.

Unless a single prior art reference describes “all of the limitations claimed” and “all of the limitations [are] arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.” *Net MoneyIN Inc. v. VeriSign Inc.*, No. 07-1565, slip op. at 17-18 (Fed. Cir. Oct. 20, 2008). A single prior art reference must “clearly and unequivocally” describe the claimed invention “without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.” *Id.* at 19 (citing *In re Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972)). Applicants respectfully assert that claims 49-51 cannot be anticipated by Schoch as Schoch does not describe “all of the limitations claimed.”

Specifically, amended claim 49 recites “determining a level of expression of each of at least five cluster-specific genes from a single cluster selected from the group consisting of clusters #9, #12, and #13, corresponding to AML classes of inv(16), t(15; 17) or t(8;21) respectively.” The Office alleges, at page 8 of the Office Action, that Schoch teaches the use of two genes from cluster #9, two genes from cluster #12, and four genes from cluster #13. Consequently, Schoch does not teach the use of “at least five cluster-specific genes from a single cluster” and therefore cannot anticipate the claims as amended.

#### Kohlmann

Claims 49-54 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Kohlmann *et al* (Genes, Chromosomes, & Cancer 2003 37:396-405) (hereinafter “Kohlmann”). Applicants traverse the rejections as hereafter set forth.

Applicants respectfully assert that claims 49-54 cannot be anticipated by Kohlmann as Kohlmann does not describe “all of the limitations claimed.” Specifically, amended claim 49 recites: “assigning to the subject a prognosis based on the established level of expression similarity between the at least five cluster-specific genes in the AML affected subject and the at least five cluster-specific genes in patients selected from the corresponding AML class.”

While Kohlmann does perform the analysis with the same Affymetrix GeneChip as disclosed in the present application, Kohlmann does not teach providing a prognosis to a patient

based on the level of five genes within a single one of the recited clusters. Kohlmann, at Tables 2 and 3, does provide a number of genes whose expression levels can, in concert, be used to classify a subject into an AML subtype. However, those genes are spread over a large number of clusters and Kohlmann does not teach that any specific five genes of a particular cluster are sufficient to provide a prognosis. Consequently, Kohlmann cannot anticipated amended claim 49.

Further, regarding claims 52-54, while Kohlmann may have analyzed the expression of the genes recited in these claims, Kohlmann does not teach that the expression levels of any of the combinations of 5 genes in claims 52-54 can used alone, without any other genes, to provide a prognosis to a subject.

In view of at least the foregoing, applicants request the withdrawal of the rejections under 35 U.S.C. § 102(b) and reconsideration of the claims.

**CONCLUSION**

In light of the above amendments and remarks, applicant respectfully requests reconsideration and allowance of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicant's attorney at the address or telephone number given herein.

Respectfully submitted,



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Enclosure:            Appendices A and B  
                         Information Disclosure Statement  
                         Annotated Sheets Showing Changes

# **APPENDIX A**

**(CLEAN VERSION OF SUBSTITUTE SPECIFICATION)**

**(Serial No. 10/590,385)**